

REMARKS

The Present Invention

The present invention pertains to nucleic acid molecules, compositions comprising the same, a recombinant expression vector, a host cell comprising the same, a method for detecting a nucleic acid encoding Rig, and a method for amplifying a nucleic acid encoding Rig.

The Pending Claims

Claims 1-4, 6-16, and 29 are pending, of which claims 1-3 are directed to a recombinant expression vector, claim 4 is directed to a host cell comprising the same, claims 6-10 are directed to a method of detecting a nucleic acid encoding Rig, and claims 11-16 and 29 are directed to a method of amplifying a nucleic acid encoding Rig.

The Office Action

The following rejections are outstanding:

- (a) claims 6-16 and 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement and written description,
- (b) claims 3 and 6-16 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite,
- (c) claims 1 and 4 under 35 U.S.C. § 102(b) as allegedly anticipated by Lamerdin et al., GenBank Accession No. AC006538 (herein referred to as Lamerdin et al.),
- (d) claims 6-15 and 29 under 35 U.S.C. § 102(b) as allegedly anticipated by Yu et al., *P.N.A.S.* 96: 214-219 (1999) (herein referred to as Yu et al.),
- (e) claims 1 and 2 under 35 U.S.C. § 103(a) as allegedly obvious in view of Lamerdin et al.,
- (f) claims 1, 3, and 4 under 35 U.S.C. § 103(a) as allegedly obvious in view of Lamerdin et al., Kimmelman et al., *Oncogene* 15: 2675-2685 (1997) (herein referred to as Kimmelman et al.), U.S. Patent 6,077,686 (herein referred to as the ‘686 patent), and Baker et al., *Nucleic Acids Res.* 25: 1950-1956 (1997) (herein referred to as Baker et al.), and
- (g) claims 1, 6-16, and 29 under 35 U.S.C. § 103(a) as allegedly obvious in view of Lamerdin et al. in combination with Kimmelman et al., alone or in further combination with U.S. Patent 4,695,188 (herein referred to as the ‘188 patent), U.S. Patent 5,981,183 (herein referred to as the ‘183 patent), U.S. Patent 5,314,809 (herein referred to as the ‘809 patent), and/or U.S. Patent 5,397,703 (herein referred to as the ‘703 patent).

Reconsideration of these rejections is hereby requested.

Amendments to the Claims

Claim 1 has been amended to replace the phrase “consisting essentially of” with the phrase “consisting of.” Claim 3 has been amended to insert a verb. Claims 6 and 11 have been amended to recite “a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5.” This amendment is supported by the specification at, for example, page 5, lines 5-7, and Example 2. Accordingly, no new matter has been added by way of these amendments.

Discussion of the Indefiniteness Rejection

Claim 3 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Patent Office contends that claim 3 lacks a verb. Claim 3 has been amended to insert a verb (i.e., “is”). Therefore, this rejection is believed to be moot.

The Patent Office has maintained the rejection of claims 6-16 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Patent Office argues that the recitation of “Rig” is unclear. In order to advance prosecution and not in acquiescence of the rejection, claims 6 and 11 have been amended to recite “a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5.” In view of these amendments, this rejection is believed to be moot.

Discussion of the Rejections Under 35 U.S.C. § 112, First Paragraph

The Patent Office has maintained the rejection of claims 6-16 under Section 112, first paragraph, as allegedly lacking enablement and written description, and further rejects claim 29 on the same bases. These rejections are traversed for the reasons set forth below.

The Patent Office specifically contends that the specification is not enabling for methods of detecting or amplifying a nucleic acid encoding a Rig polypeptide other than the nucleic acid having the nucleotide sequence of SEQ ID NO: 5, namely because the term “Rig polypeptide” renders the scope of the claims unclear. The Patent Office also contends that the scope of the claims is unclear, as the specification fails to give an adequate definition of what is and what is not a Rig polypeptide. The Patent Office further argues that it is unclear as to whether or not the 8 Ras-related polypeptides disclosed in the specification are considered Rig polypeptides. However, as discussed in the “Amendment and Response to Office Action” dated July 25, 2003, one of ordinary skill in the art is, in fact, able to make a determination as to what is and is not a Rig protein, given all of the teachings on the Rig protein in the specification. Also, as the specification teaches that the Rig protein is predicted

to have the amino acid sequence of SEQ ID NO: 5 (see Figure 1, for example) and since the 8 Ras-related polypeptides disclosed in the specification have different amino acid sequences, it is clear to one of ordinary skill in the art that the 8 Ras-related polypeptides are not considered to be the Rig protein. The specification, moreover, teaches how to detect a nucleic acid encoding a Rig polypeptide at, for instance, page 45, line 6, through page 46, line 18, and page 79, line 17, through page 80, line 15, and teaches how to amplify a nucleic acid encoding a Rig polypeptide at, for example, page 17, line 15, through page 18, line 27, and page 78, lines 7-19.

However, in order to advance prosecution and not in acquiescence of the rejections, claims 6 and 11 have been amended to recite “a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5.” In view of these amendments, these rejections are believed to be moot.

Discussion of the Rejections Under 35 U.S.C. § 102

The Patent Office has maintained the rejection of claims 1 and 4 under Section 102(b) as allegedly anticipated by Lamerdin et al. This rejection is traversed for the reasons set forth below.

The Patent Office specifically contends that Lamerdin et al. discloses a bacterial artificial chromosome (BAC) comprising 177 kb of human chromosome 19, including a segment encoding the amino acid sequence of SEQ ID NO: 5, and 105 kb of upstream genomic sequence. The Patent Office concludes “it is clear that this nucleic acid comprises the transcriptional control elements for this open reading frame. For this reason, the bacterial artificial chromosome ... is an expression vector for SEQ ID NO: 5” (see page 14 of Paper No. 13). Furthermore, with respect to the phrase “consisting essentially of” in claim 1, the Patent Office states that Applicant has provided no evidence or argument that the BAC of Lamerdin et al. materially affects the basic and novel characteristics of the claimed invention in any way, and the specification provides no indication of what is essential to the basic and novel characteristics of the claimed invention.

In order to advance prosecution and not in acquiescence of the rejection, claim 1 has been amended to replace the phrase “consisting essentially of” with “consisting of.” The phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. (see, e.g., MPEP § 2111.03). Thus, claim 1, as amended, requires a recombinant expression vector *consisting of* an open reading frame encoding SEQ ID NO: 5 and one or more regulatory elements. Since Lamerdin et al. discloses a vector containing over 177 kilobasepairs, parts of which encode at least 9 other predicted exons and at least 2 other

proteins, Lamerdin et al. does not disclose a recombinant expression vector *consisting of* an open reading frame encoding SEQ ID NO: 5 and one or more regulatory elements. As such, Lamerdin et al. does not anticipate the subject matter of claim 1, or claims 2-4 depending therefrom. Accordingly the Section 102 rejection of claims 1 and 4 should be withdrawn.

The Patent Office also has maintained the rejection of claims 6-15 under Section 102(b) as allegedly anticipated by Yu et al., and further rejects claim 29 on the same basis. This rejection is traversed for the reasons set forth below.

The Patent Office specifically alleges that Yu et al. discloses detection of a poly mRNA from human tumor tissue of a nucleic acid encoding Noey2, a polypeptide that is 63% identical to SEQ ID NO: 5. The Patent Office further asserts that Yu et al. discloses identification of a Noey2 gene in genomic DNA. The Patent Office concludes that, because the specification allegedly does not exclude Noey2 from the genus of polypeptides that may be construed as a Rig polypeptide, Yu et al. anticipates a method of detecting nucleic acids encoding Rig in a sample. Claims 6 and 11 have been amended to recite “a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5.” Yu et al. do not disclose detection of a Rig protein having an amino acid sequence as set forth in SEQ ID NO: 5. Therefore, Yu et al. does not anticipate the subject matter of claims 6 and 11, or claims depending therefrom. Accordingly, the Section 102 rejection of claims 6-15 and 29 should be withdrawn.

Discussion of the Rejections Under 35 U.S.C. § 103

The Patent Office has maintained the rejection of claims 1-4, 6-16, and 29 under Section 103(a) as allegedly being obvious in view of Lamerdin et al., alone or in combination with one or more of Kimmelman et al., the ‘686 patent, Baker et al., the ‘188 patent, the ‘183 patent, the ‘809 patent, and/or the ‘703 patent. These rejections are traversed for the reasons set forth below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The cited references do not disclose or suggest all of the claim limitations recited in

the pending claims. As discussed above, Lamerdin et al. does not disclose or suggest a recombinant expression vector *consisting of* an open reading frame encoding SEQ ID NO: 5 operably linked to one or more regulatory elements as recited in claim 1, and claims depending therefrom. Moreover, none of the disclosures of Kimmelman et al., the '686 patent, Baker et al., the '188 patent, the '183 patent, the '809 patent, or the '703 patent cures the deficiency of Lamerdin et al., i.e., none teach a recombinant expression vector *consisting of* an open reading frame encoding SEQ ID NO: 5 operably linked to one or more regulatory elements.

Claims 6 and 11, and claims depending therefrom, require detecting and amplifying, respectively, a nucleic acid encoding a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5 in a sample. Lamerdin et al. does not disclose or suggest a method of detecting or amplifying a nucleic acid encoding a Rig protein of SEQ ID NO: 5. Moreover, none of the disclosures of Kimmelman et al., the '188 patent, the '183 patent, the '809 patent, and the '703 patent cures the deficiencies of Lamerdin et al., because none of these references discloses or suggests methods for detecting or amplifying a nucleic acid encoding a Rig protein having the amino acid sequence set forth in SEQ ID NO: 5.

Because the cited references do not disclose or suggest every element of claims 1-4, 6-16, and 29, alone or in combination, the cited references do not render the subject matter of these claims obvious. Therefore, the Section 103 rejections should be withdrawn.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,


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